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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,957	04/19/2006	Soledad Penades	0380-P03930US0	1468
110 7590 11/23/2010 DANN, DORIMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307				
EXAMINER				
DO, PENSEE T				
ART UNIT		PAPER NUMBER		
1641				
MAIL DATE		DELIVERY MODE		
11/23/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/559,957

**Applicant(s)**

PENADES ET AL.

**Examiner**

Pensee T. Do

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29, 31-33 and 52-80 is/are pending in the application.
- 4a) Of the above claim(s) 1-29, 31-33, 52-69 and 73-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29, 31-33 and 52-80 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

This application 10559957, PG Pub. No. 20060233712 filed 04/19/2006 is a national stage entry of PCT/GB04/02408 , International Filing Date: 06/07/2004 claims foreign priority to 0313259.4 , filed 06/09/2003.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Amendment Entry & Claims Status***

The amendment filed on September 2, 2010 has been acknowledged and entered.

Claims 70-72 are being examined.

Claims 1-29, 31-33, 52-69 and 73-80 are withdrawn from further consideration.

Claims 30, 34-51 are cancelled.

### ***Claimed Invention***

70. (Currently Amended) A method for performing magnetic resonance imaging (MRI) of a site in a patient, said method comprising administering to said patient a MRI contrast agent comprising nanoparticles, said nanoparticles having a core of metal atoms, wherein the core is covalently linked to a plurality of ligands and has a diameter of less than 2.5 nm, and wherein said ligands incorporate or chelate a lanthanide.

### ***Rejection(s) Withdrawn***

All rejections under 102 and 103 in the previous office action are withdrawn herein.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 70-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Hainfield et al. (US 6,955,639 filed on March 12, 2003).

Hainfield teaches a method of administering MRI nanoparticles to a site in a patient, said method comprises using metal nanoparticles having a core of metal atoms (see col. 8, line 61-col. 9, line 52) wherein the core is covalently linked to a shell comprising a plurality of ligands (see col. 10, lines 3-42), wherein the core has a diameter size range from 0.5 to 400 nm which covers the limitation of less than 2.5 nm. (see col. 9, lines 12-14); and wherein the ligands chelate a lanthanide (see col. 10, lines 36-42). Hainfield teaches that the shell is DTPA which chelates gadolinium metals- which are lanthanide metals . The shell is equivalent to the plurality of ligands claimed in

the present invention. Hainfield also teaches that the shell can also include molecules such as sugar compounds, sugar polymers (see col. 10, lines 8-14) or the shell is linked to a lipid, antibody, carbohydrate, nucleic acids, etc. (see col. 10, lines 12-35).

For claim 71, Hainfield teaches the metal nanoparticles are administered intravenously, intra-arterially or locally to achieve specific loading in and around the target tissue. (see abstract). Thus, the target tissue can be any body part in a patient including the lungs.

For claim 72, Hainfield teaches the nanoparticles comprise gadolinium (see col. 9, line 26) and have a core diameter of less than 1.0 nm. (see col. 9, lines 12-16).

### ***Response to Arguments***

Applicant's arguments with respect to claims 70-72 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the reference Hainfield, Applicants submit that Hainfield provides a very limited discussion of MRI since Hainfield is primarily concerned with enhancing radiation effects. There is also no suggestion or teaching in any of the cited references to provide nanoparticles having a metal core covalently linked to a plurality of ligands, wherein the ligands incorporate or chelate a lanthanide. (see response 9/2/2010 page 11).

Hainfield although provides limited discussion of MRI, provides a method of administering the nanoparticles comprising a metal core which is covalently linked to a plurality of ligands/shells which are further linked to a plurality of ligands. The shell-linked ligands comprise a metal chelator which is DTPA and therefore satisfies the

requirement of the newly added limitation in claim 70. This DTPA chelates a lanthanide such as gadolinium. (see Hainfield col. 9, lines 36-43).

Although, Hainfield was previously applied as a secondary in an obviousness rejection, Hainfield now is applicable as an anticipation reference because Hainfield teaches all the required limitation of claims 70-72.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on **Monday-Friday, 9-5**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/  
Examiner, Art Unit 1641

/Jacob Cheu/  
Primary Examiner, Art Unit 1641